NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ANDREW NELSON, **Plaintiff,** **v.** **BIOGEN IDEC, INC. and ELAN PHARMACEUTICALS, LLC,** **Defendants.**	**Civil Action No. 12-7317 (JMV)** **OPINION**

FALK, U.S.M.J.

Plaintiff, Andrew Nelson, filed the original Complaint in this matter on November 28, 2012, alleging that he sustained serious injuries stemming from his use of Defendant's FDA-approved drug Tysabri®, which was prescribed to him for the treatment of multiple sclerosis. Following motion practice, Plaintiff's remaining claim is one for failure to warn under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-2.

Plaintiff has moved for leave to file a fourth amended complaint. [ECF No. 121.] The motion is opposed. For the reasons stated below, the motion is **GRANTED**.

I. Background

Plaintiff suffers from multiple sclerosis (MS). He was prescribed Defendant's drug Tysabri to help treat his MS. One of the possible side effects of Tysabri is an

increased risk of contracting a devastating neurological disease known as progressive multifocal leukoencephalopathy ("PML"). Plaintiff developed PML, which severely disabled him. The proposed amended complaint focuses on a test known as a JC Virus antibody assy, which can help predict whether a person taking Tysabri would develop PML. In overly simplified terms, Plaintiff alleges that Defendants' activities and negligence in connection with the development of the JC Virus Antibody test makes Defendants liable for Plaintiff's injuries. Basically, Plaintiff claims had Defendants met their obligations and developed the test earlier, it would have enabled him to decide not to take Tysabri or discontinue its use prior to developing PML. Once again, the above description is a summary oversimplification of complex scientific issues.

There are a number of nearly identical cases around the country between Tysabri Plaintiffs and Defendants. The same lawyers and certain experts are involved in all of the cases. On May 11, 2016, in a case pending in the District of Utah, Magistrate Judge Dustin B. Pead denied a very similar motion to amend.[1] On May 20, 2016, Plaintiff's counsel (in both cases) submitted a letter stating that Plaintiff is appealing the Magistrate Judge's Opinion in Utah as "clearly erroneous and contrary to law."

[1] *Christison v. Biogen Idec, Inc.*, *et al.*, No. 11-cv-1140-DN-DBP. Plaintiff Christison died, allegedly from PML.

II. Plaintiff's Motion to Amend[2]

Plaintiff seeks leave to amend his Complaint to bring a common law claim of negligent undertaking. Plaintiff's claim is based on the allegation that Defendants were negligent in failing to promptly follow up and offer the JC Virus antibody assay, notwithstanding their alleged undertaking to do so as early as 2006. The proposed amendment is allegedly based on information in a Biological Materials Licensing Agreement (MLA) by which Biogen received the JCV antibody assay and samples which would enable the test to be used effectively.

Plaintiff's motion comes after the deadline for amending pleadings contained in the Court's Scheduling Order. The reason offered for the late amendment is "newly produced evidence"—the License Agreement between Defendant Biogen and the National Institute of Health, which was first produced by Defendant on September 28, 2015, following the deposition of Plaintiff's expert. (Pl.'s Br. 1.)

The License Agreement with NIH, dated October 19, 2006, licensed to Biogen the use of "serologic assays for the detection and differentiation of antibodies directed against JC or BK viruses." Plaintiff claims that Defendants knew that the JC Virus causes PML, and that the License Agreement proves that, in 2006, Biogen had technology to test the blood for JC Virus antibodies. Yet, instead of moving expeditiously, Plaintiff claims that Defendants made a financially-motivated decision to develop their own version of the

[2] Aspects of this Opinion are drawn from the parties' briefs, declarations, and letters. Many of the submissions contain cross-reference and citation to documents in the *Christison* lawsuit pending in the District of Utah.

assay, which was eventually released in January 2012. Plaintiffs allege that Defendants voluntarily assumed the duty to develop and commercialize an antibody assay, and were negligent in their execution of that duty. (Pl.'s Br. 1-3.)

Defendants counter that Plaintiff's proposed amendment is untimely and that Plaintiff has not shown "good cause" to amend the scheduling order and allow the late claim. (Defs.' Br. 11-15.) They also claim that the amendment is prejudicial, brought to avoid summary judgment and prolong the case, and futile for a number of reasons—including that New Jersey does not recognize a claim for negligent undertaking on these facts; that a common law claim for negligent undertaking is preempted by federal law; and that public policy bars the type of negligence claim proposed in this case. (Defs.' Br. 15-26.)

III. Decision

A. Plaintiff Has Shown Sufficient Good Cause

The legal standard for amending pleadings is extremely liberal. The Amendment is usually permitted unless the party opposing amendment can show genuine prejudice. When the request to amend comes after an amendment deadline in a scheduling order, a higher standard applies requiring a showing of "good cause."

The deadline to amend pleadings in this case was June 14, 2014. Therefore, Plaintiff's motion implicates not only Rule 15, but also Rule 16(b)'s "good cause" requirement. Dimensional Commc'n Inc. v. Oz Optics, Ltd., 148 Fed. Appx. 82, 85 (3d

Cir. 2006).[3] Good cause largely depends on the diligence of the moving party. Harrison Beverage Co. v. Dribeck Importers, Inc., 133 F.R.D. 463, 469 (D.N.J. 1990). The movant must show that "despite its diligence, it could not reasonably have met the scheduling order deadline." Hutchins v. United Parcel Service, No. 01-1462, 2005 WL 1793695, at *3 (D.N.J. July 26, 2005).

What will constitute "good cause" to warrant modification "necessarily varies with the circumstances of each case." 6A Alan Wright et al., Federal Practice & Procedure § 1522.2 at 313 (3d ed. 2010). The Court, therefore, has "great discretion in determining what kind of showing the moving party must make in order to satisfy the good cause requirement of Rule 16(b)." Thoman v. Philips Med. Sys., No. 04-3698, 2007 WL 203943, at *10 (D.N.J. Jan. 24, 2007) (citations omitted).

Plaintiff claims that "good cause" supporting the amendment is Defendants' late production of the NIH-Biogen License Agreement in September 2015. Defendants counter that the License Agreement does not constitute good cause because Plaintiff was inferentially aware of the existence of the NIH transfer before the actual License Agreement was produced. Specifically, Defendants point to the May 2015 report of Plaintiff's expert, Dr. Eugene O. Major, which contains a general reference to the

[3] Rule 16(b)(4) provides in relevant part: "A schedule may be modified only for good cause."

existence of a transfer agreement relating to assay technology.[4]

It is true that Dr. Major's report refers to a licensing arrangement. However, it is not a very detailed reference to what is a complicated agreement and the agreement wasn't attached to the report. Also, there is a disconnect between what Plaintiff knew and what one of his experts knew. Indeed, in a declaration submitted with the motion to amend, Dr. Major explains that he did not disclose to Plaintiff his knowledge relating to the License Agreement:

> [t]here are multiple reasons for the absence of discussion between myself and the Plaintiff regarding the MLA. First, although I possessed general knowledge that a transfer occurred, I had no specific knowledge regarding the terms and or conditions of the MLA; . . . . Additionally, I abstained from disclosing any information that I may have possessed about the MLA or its transfer of materials in an abundance of caution and respect for ethical and professional standards. As the Court is aware, the Defendants previously attempted to disqualify me as an expert witness in this case based on: . . . [2] Tysabri-related work I performed with Biogen during my time at NIH. I submitted an affidavit at that time to make clear my testimony would be based on my general experience and expertise in virology and the development of ELISA assays and not about the specific information acquired in the courts of performing my official duties at the NIH.

(Affidavit of Eugene O. Major at 6; ECF No. 127-1.)

Plaintiff's expert knew of the License Agreement; but Plaintiff did not. Moreover, even Plaintiff's expert swears he "had no specific knowledge regarding the terms and

[4] Dr. Major's report itself was served well after the 2014 Amendment deadline.

conditions of the license agreement." Id. Thus, Plaintiff was unaware of the specifics of the License Agreement until after the document was produced. It is unfair to claim that Plaintiff should have sought leave to amend based on the specifics of the License Agreement without having seen the document. Indeed, it is not inconceivable that Defendants could have argued that Plaintiff lacked a good faith factual basis for the Amendment prior to getting the License Agreement.

The parties disagree on Plaintiff's diligence and just how important the License Agreement is to pleading the negligent undertaking claim. Nevertheless, good cause is case dependent and highly discretionary. See Thoman, 2007 WL 203943, at *10 (the Court has "great discretion in determining what kind of showing the moving party must make in order to satisfy the good cause requirement of Rule 16(b)."). And it appears that:

- Biogen produced the License Agreement in September 2015, long after the deadline to amend;
- the License Agreement contains multiple terms that are "both new information as well as pertinent to the claim for negligent undertaking";
- Plaintiff's knowledge of the License Agreement was minimal and lacking context (at most) until the Agreement was produced;
- Plaintiff's expert has forcefully stated that he did not inform Plaintiff about the terms of the License Agreement because he himself did not know the

specifics and because of ethical obligations relating to his prior employment; and

- Plaintiff requested the License Agreement from Defendants earlier in discovery and it was mistakenly represented that it had been produced.

Based on these assertions, the Court is satisfied that Plaintiff has shown sufficient good cause for seeking to amend after the deadline in the scheduling order.[5] More specifically, Plaintiff has strongly demonstrated that, without the Licensing Agreement, he could not have met the Scheduling Order deadline. This is especially so in such a complex scientific realm when pleading a somewhat adventurous claim.

B. No Undue Prejudice

"Prejudice to the non-moving party is the touchstone for the denial of an amendment." Lorenz v. CSX Corp., 1 F.3d 1406,1414 (3d Cir. 1993). Incidental prejudice is insufficient grounds on which to deny leave to amend. See In re Caterpillar, Inc. , 67 F. Supp. 3d 663, 668 (D.N.J. 2014). Prejudice is generally evaluated by looking at whether the amendment would: (1) require the non-moving party to expend significant additional resources to conduct discovery and prepare for trial; (2) significantly delay the resolution of the dispute; or (3) prevent the non-moving party from bringing a timely

[5] The Court acknowledges that Magistrate Judge Pead denied a similar motion to amend in the *Christison* case on May 11, 2016, finding that the plaintiff failed to establish good cause. The plaintiff is appealing that decision, which remains pending. While the facts and arguments may be similar, a different conclusion on "good cause" is reached here, which is largely discretionary.

action in another forum. See, e.g., Long v. Wilson, 393 F.3d 390, 400 (3d Cir. 2004).

Plaintiff's proposed amendment is not unduly prejudicial. No new parties are being brought into the case. Rather, a new legal theory is being added. Importantly, it does not appear that the amendment will require significant additional discovery. Plaintiff claims that the amendment arises out of the same subject matter contained in the original complaint, i.e., testing for the JC Virus antibodies, which has already been the subject of extensive discovery. By contrast, Defendants claim that significant additional discovery will be needed, but no specifics are provided. (Defs.' Br. 15-16.) As best as the Court can tell, to the extent additional discovery is required, it appears to be limited to one or two depositions, perhaps including that of Dr. Major. This does not constitute "undue" prejudice; indeed, any additional discovery could be promptly conducted under the management of the Magistrate Judge. To the extent there is any delay or prejudice present, it is insufficient to overcome the liberality associated with the amendment of pleadings.

C. No Clear Futility

The futility analysis on a motion to amend compares to a Rule 12(b)(6) motion. See In re NAHC, Inc. Sec. Litig., 306 F.3d 1314, 1332 (3d Cir. 2002) ("An amendment would be futile when 'the complaint, as amended, would fail to state a claim upon which relief could be granted.'"). For a complaint to survive dismissal, it "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its

face.'" Ashcroft v. Iqbal, 556 U.S. 662 (2009) (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570, (2007)). Given the liberal standard for the amendment of pleadings, "courts place a heavy burden on opponents who wish to declare a proposed amendment futile." Pharmaceutical Sales and Consulting Corp. v. J.W.S. Delavau Co., Inc., 106 F. Supp. 2d 761, 764 (D.N.J. 2000) (citations omitted). Although tracking Rule 12(b)(6), Rule 15 futility does not contemplate substantive motion practice on the merits of the claims:

> If a proposed amendment is not ***clearly*** futile, then denial of leave to amend is improper. This does not require the parties to engage in the equivalent of substantive motion practice upon the proposed new claim or defense; this does require, however, that the newly asserted defense appear to be sufficiently well-grounded in fact or law that it is not a frivolous pursuit.

Harrison Beverage Co. v. Dribeck Importers, Inc., 133 F.R.D. 463, 468 (D.N.J.1990) (emphases added) (citations omitted); see also 6 Wright, Miller & Kane Federal Practice and Procedure, §1487 (2d ed. 1990). Effectively, this means that the proposed amendment must be "frivolous or advance a claim or defense that is legally insufficient on its face . . . ." Marlowe Patent Holdings, LLC v. Dice Electronics, LLC., 293 F.R.D. 688, 695 (D.N.J. 2013).

Defendants forcefully argue that the proposed amendment is futile for numerous reasons, including that: New Jersey law does not recognize a negligent undertaking claim in the circumstances present here; Defendants had no duty to develop a JCV antibody

assay; and Plaintiff's claim is preempted by federal law. Plaintiff has a credible response to all of these arguments, including that a jury should decide Defendants' obligations under the somewhat unique facts presented.

In this Court's view, the futility arguments made all go beyond the scope of what is appropriate in the context of a motion to amend. Defendants' futility arguments are claim dispositive issues focused on, for example, federal preemption and the obligations imposed on pharmaceutical companies by the FDA. Deciding such arguments in the context of a non-dispositive, Rule 15 motion to amend pleadings arguably usurps the authority of a District Judge deciding a Rule 12(b)(6) motion; stated differently, it is making an embedded dispositive decision in the context of a facially non-dispositive motion. The Court does not believe that is the contemplation of Rule 15 motion practice.

The amendment is somewhat sophisticated and presented against a background of intricate scientific principals and heavy governmental regulation of a pharmaceutical industry where the rules and practices have been changing over time. It is no doubt an enterprising claim. However, we cannot conclude that the claim is clearly futile on its face. Defendants' claims of futility may ultimately be correct; if so, Plaintiff's claim will fall. But that decision requires a more searching analysis than is called for by Rule 15, where the futility analysis speaks of patent frivolousness on the face of the pleading. Harrison Beverage Co., 133 F.R.D. at 468. We do not have that here. The proposed amendment is the subject of some forceful merits-based attack, but not one that is "legally

insufficient on its face." Marlowe Patent Hold., 293 F.R.D. at 695. For purposes of Rule 15 only, the Court is satisfied that Plaintiff's proposed amendment is not futile.

CONCLUSION

For the reasons stated above, Plaintiff's motion to amend [ECF No. 121] is **GRANTED**. The pleading should be filed within 7 days. Defendants may respond to the pleading in any manner authorized by the Federal Rules of Civil Procedure.

SO ORDERED.

s/Mark Falk
MARK FALK
United States Magistrate Judge

Dated: June 7, 2016